



Food and Drug Administration
10903 New Hampshire Avenue
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Conventus Orthopaedics, Incorporated
Mr. Kent Lind
Vice President Quality, Regulatory, Clinical
10200 73rd Avenue North, Suite 122
Maple Grove, Minnesota 55369

April 8, 2015

Re: K141737
Trade/Device Name: Conventus PHSTM System
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: Class II
Product Code: HSB, HRS
Dated: March 17, 2015
Received: March 17, 2015

Dear Mr. Lind:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K141737

Device Name: Conventus PHS™ System

The Conventus Orthopaedics PHS™ System is indicated for the fixation of proximal humerus fractures except when there are too many fracture fragments to repair the articular surface.

Prescription Use √
(Part 29 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(29 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

5. 510(k) Summary

Company: Conventus Orthopaedics, Inc.
10200 73rd Avenue North, Suite 122
Maple Grove, MN 55369

Device Trade Name: Conventus PHS™ System

Device Common Name: Proximal humerus fracture fixation system

Contact: Kent R. Lind
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Prepared By: Musculoskeletal Clinical Regulatory Advisers, LLC
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Phone: (202) 552-5800
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Date Prepared: April 3rd, 2015

Classification: 21 CFR 888.3030, Single/multiple component metallic bone fixation appliances and accessories
21 CFR 888.3020: Intramedullary fixation rod

Class: II

Product Codes: JDS and HRS

Indications for Use: The Conventus Orthopaedics PHS™ System is indicated for the fixation of proximal humerus fractures except when there are too many fracture fragments to repair the articular surface.

Device Description: The Conventus PHS™ is an intramedullary device intended to treat proximal humerus fractures. The PHS™ System is a self-expanding implant which is deployed into the medullary canal and provides a scaffold to which bone fragments are attached using fragment screws. The implant is made from titanium alloy (Ti-6Al-4V ELI) and Nitinol.

Substantial Equivalence: Conventus Orthopaedics has demonstrated that, for purposes of FDA's regulation of medical devices, the Conventus PHS™ System

is substantially equivalent to the following devices that have been previously cleared by the FDA:

- DePuy ACE TiMAX Meta Plate (K983853)
- Synthes Titanium Cannulated Humeral Nail System (K033071)
- Conventus Orthopaedics, Inc. DRS™ System (K102689)

This finding is supported by the following pre-clinical tests that have been performed:

- Static and cyclic axial/bend testing
- Static and cyclical torsional testing
- Screw pullout testing
- Corrosion testing
- Wear testing
- Nickel ion release testing
- Surface analysis testing
- Nitinol phase composition
- Nitinol transition temperature (A_f)
- Biocompatibility testing
- Animal testing

The results demonstrate that the PHS™ System is substantially equivalent to the legally marketed predicate devices.